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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,641	04/01/2005	Makoto Asakawa	SHIM1100	6517

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EXAMINER	
GUZO, DAVID	
ART UNIT	**PAPER NUMBER**
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/762,641	ASAKAWA ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/18/07 has been entered.

35 USC 103(a) Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Magi et al. in view of Zhang et al. or Nabel et al.

This rejection stands for reasons of record in the previous Office Action (mailed 9/5/07) and for reasons outlined below.

Applicants traverse this rejection by asserting that the Magai et al. reference fails to disclose that the cells comprising a Sendai virus RNA expressing viral proteins other than M protein are capable of introducing the transgene to a neighboring cell by contact. Applicants argue that it is not clear how one of skill in the art would have understood that the expressed F protein mediates transfer of the transgene to a neighboring cell by contact. Applicants argue that it is not clear how one of skill in the art, in view of Magai, would have understood that the host cells comprising said complex would be able to fuse with neighboring cells and applicants assert that Magai is absolutely silent with regard to the ability of a specific species of virus to expand the transgene from the infected cell to the neighboring cell through cell-to-cell contact. Applicants also again assert that Magai et al. teaches away from the instant invention in that Magai et al. expressly indicates that, "[s]ince said complexes can replicate only within infected cells but not spread from cell to cell, these techniques are especially useful in the fields of gene therapy, etc. wherein therapeutical safety is highly appreciated." Finally, applicants assert that both Zhang and Nabel are equally silent with regard to suggesting that a non- segmented (-)RNA virus which lacks a gene encoding M protein or comprises an inactivated gene encoding M protein is incapable of transferring its genome by infectious particles but is capable of transferring its genome by contact

infiltration and applicants assert that since the combined references do not teach each and every limitation of the amended claims, prima facie obviousness of the invention over Magai et al., Zhang et al. or Nabel et al., either alone or in combination, has not been shown by the Office.

Applicant's arguments filed 10/18/07 have been fully considered but they are not persuasive. The disclosure of Magai et al. discloses a Sendai viral genome with a deleted M gene, this renders the virus incapable of forming infectious virions in cells containing said viral genome. Applicants' disclosure also recites a Sendai viral genome with a deleted M gene, thus rendering the virus incapable of forming infectious virions in cells containing said viral genome. The teachings of Magai et al. and applicants **both** recite introducing a ribonucleoprotein comprising an RNA of the Sendai virus (and a transgene) into target cells wherein the Sendai viral nucleic acid expresses viral proteins such as the F and HN proteins but not the M protein and hence infectious virions are not produced. The Sendai viral RNA (and transgene) would be expected to be transferred to neighboring cells by contact infiltration because the F and HN proteins of the Sendai virus are expressed in the host cells by the viral constructs disclosed by applicants and Magai et al. Indeed, with regard to the mechanism by which the viral RNA is introduced into neighboring cells by contact infiltration, applicants themselves, in specification paragraph [0072], indicate that:

> This mode of propagation is probably due to cell fusion mediated by F and HN proteins. Namely, among proteins encoded by Sendai virus, F and HN proteins are expressed as a membrane protein on the cell surface, and M protein supports F and HN proteins as an intracellular anchor in virus budding.. In case of the M deletion type and M defect type, budding does not occur because the anchor is lost. However, F and HN proteins are expressed on the cell surface, and cell fusion occurs mediated by these

proteins, so that virus genome can be transferred into surrounding cells. In this way, it is possible to realize virus propagation without budding (Figure 9).

Since the Sendai virus constructs recited by Magai et al. comprise the viral genome, including the F and HN genes, minus a deleted M gene, the person of ordinary skill in the art would expect, absent evidence to the contrary, that the Sendai viral F and HN genes would be expressed in the target cell and the gene products of these two Sendai viral genes would mediate cell fusion, as contemplated by applicants' disclosure, and hence mediate transfer of the viral RNA (and transgene) into neighboring cells by contact infiltration. While the Magai et al. reference is silent about this, the methodologies taught by Magai et al. would be expected to result in transfer of the Sendai viral RNA (and transgene) to neighboring cells by contact infiltration because the mechanism of fusion of neighboring cells with cells expressing the Sendai viral F and HN proteins is an inherent biological process which would occur whether or not it is explicitly recited in the reference.

The portions of the Magai et al. reference which applicants indicate teach away from the claimed invention refer to the inability of the complexes to produce infectious virus particles and hence the inability of the complexes to spread from cell to cell by virus infection. This portion of the Magai et al. reference does not teach away from the present invention because Magai et al. was referring to viral replication and the fact that the viruses cannot spread from cell to cell by **generation of infectious virions**.

The teachings of Zhang et al. or Nabel et al., therefore, in combination with the teachings of Magai et al., render the instant invention obvious.

Any rejections not repeated in this Office Action are withdrawn.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
October 27, 2007

DAVID GUZO
PRIMARY EXAMINER